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PATENT SPECIFICATION

DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

Wound Edge Protector

We, JOHNSON & JOHNSON, a Corporation of the State of New Jersey, United States of America, located at 501 George Street, New Brunswick, New Jersey, United States of America, do hereby declare the invention, for which we pray that a Patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to improvements in surgical wound protection.

An object of the present invention is to provide an improved wound edge protector wherein an entire surgical wound surface is protectively covered.

Another object of the present invention is to provide an improved wound edge protector which can be inserted easily into a surgical wound cavity so as to cover the entire peripheral surface as well as adjacent inner and outer surface portions thereof.

Still another object of the present invention is to provide an improved wound edge protector according to the previous object wherein the space occupied thereby is minimal and the protector is transparent so that the surgeon can see and work as though no protector were in use.

A further object of the present invention is to provide an improved wound edge protector in accordance with foregoing objects wherein the protector is self-retaining so as to obviate the need for any sutures or other holding devices.

A still further object of the present invention is to provide an improved wound edge protector which is:

- (a) Impervious to moisture, body fluids, bacteria and cancer cells.
- (b) Non-irritating to wound surfaces.
- (c) Strong but pliable to conform to wound contour and to allow for purposeful distortion of the wound by retractors.
- (d) Readily sterilized or is disposable.
- (e) Capable of being inverted upon itself so

as to cover the organs within the wound to facilitate closure of the wound.

Still another object of one embodiment of the present invention is to provide an improved wound edge protector which is adjustable to various size incisions.

Various other objects and advantages will become apparent from the detailed description to follow:

In the drawings

Figure 1 is a plan view of a wound edge protector according to the present invention;

Figure 2 is a side elevational view thereof;

Figure 3 is a side elevational view thereof in a compressed form;

Figure 4 is an end elevational view of the protector shown in Figure 1;

Figure 5 is a detail sectional view taken substantially along the plane of line 5—5 in Figure 4;

Figure 6 is a perspective view showing the protector in place in use, with part in section;

Figure 7 shows the protector in a "folded over" form.

Figure 8 is a plan view showing a wound edge protector according to the adjustable embodiment of the present invention;

Figure 9 is a side elevational view of the embodiment of Figure 8;

Figure 10 is a vertical sectional view taken substantially on the plane of Line 3—3 in Figure 8;

Figure 11 is a perspective view of the embodiment of Figure 8 partially broken away, and showing the adjusting means;

Figure 12 is an exploded perspective view of the embodiment of Figure 8 showing a modified form of adjusting means;

Figure 13 is a perspective view showing the adjustable embodiment of the protector in use, part being cut away;

Figure 14 is an enlarged detail longitudinal sectional view through certain of the telescoping adjusting means of Figures 8—11.

Referring more particularly to Figures 1—7

[F]

of the drawings wherein like numerals apply to like parts throughout, it will be seen that we have provided an improved wound edge protector 10 which can be manufactured in a number of sizes for use in incisions of similar variations in size.

The protector 10 is comprised of a pair of flexible rings 12, 14 joined by a thin sheet 16 of flexible material formed to tubular shape. The rings can be performed to endless shape or formed by lengths of stock arcuated and joined at their ends, as by clips, not shown. In any event the stock should have sufficient preforming to give a generally oval shape, as viewed in Figure 1, yet be resilient and flexible so as to be easily flexed for insertion through a wound opening as will presently be described. There are a number of suitable plastics from which the rings can be made e.g. a polyamide such as Nylon or a polytetrafluoroethylene such as "Teflon" (Registered Trade Mark).

The thin sheet is preferably made of a plastic which has certain physical and chemical characteristics. The plastic must be impermeable to fluids and bacteria, physiologically inert, unaffected by autoclaving or sterilization in ethylene oxide, free of electrostatic hazard, resistant to melting, non-flammable if touched by cautery, and somewhat elastic. Also, the material must be formable in thin, transparent, and flexible sheets. Polyvinyls are highly suitable plastics for this purpose and have been found in actual tests to fill the requirements set forth.

The tubular form of the sheet 16 can be effected by preforming stock to that shape or, preferably, by forming a flat sheet of predetermined width to cylindrical form and sealingly overlapping the ends as at 18, in Figure 2. The longitudinal side edges then, respectively, can be folded about the rings and sealed as at 20, in Figure 5, to thus provide a unitary structure ready for sterilization and packaging.

For the purpose of packaging, the protector can be compressed with one ring 12 against the other ring 14 as shown in Figure 3.

In use, the wound protector 10 is especially useful in abdominal incisions. Figure 6 shows a portion of a patient's abdomen at A which an incision having been made. The layers through which the incision is made include the skin 22, subcutaneous tissue 24, anterior fascia 26, muscle 28 and peritoneum 30. At the incision these layers and the adjacent interior and exterior surfaces 32, 34, respectively, constitute the wound edge. The wound edge is subject to contamination by the hands, retractors or other instruments which must be introduced through the wound opening. The wound edge can be "soiled" whenever the biliary, intestinal, or genitourinary tracts are opened or a cyst or abscess drained.

In the past, a surgeon has customarily wrapped a laparotomy pad over each side of

the wound but this has proved unsatisfactory because the pads become moist, slip out of position and are bulky. Prior alternatives of rubber dam or plastic sheeting have proved unsatisfactory unless sewed to the peritoneum, which takes time.

The protector of the present invention has been found ideally suited to the needs of wounds such as here described.

The wound edge protector, after the incision is made, is squeezed together so that one of the rings 14 has its longitudinal side portion 36, 38 pressed together. The ring 14 can thus be inserted through the wound opening and allowed to expand to its normal form within the wound. The ring 14 will thus be positioned on the inside of the peritoneum 30 over the surface portion 32 as seen best in Figure 6. The outer ring 12 will naturally similarly overlap the skin edge surface at 34 and the sheet 16 will contact the entire wound surface and protectively cover the same and seal it from contamination and infection. Obviously, the protector utilizes substantially no space and aids in holding the wound open.

After the surgeon has completed his work in the wound, the wound edge protector serves an additional important function. The intestines at 40 must be held in when the surgeon closes the wound. To do this, the ring side portion 42 is folded over beneath the other ring side portion 44 to adjacent the ring side edge portion 38 and the portion 44 is folded back over to adjacent the ring side portion 36. Thus the upper or outer ring is inverted and positioned within the wound and the plastic sheet is stretched across the center of the wound. Figure 7 shows the protector when so folded. The surgeon can then close the wound except for a small end opening through which the protector is extracted and then closing is completed.

By way of information, the thickness of the abdominal wall may vary from one to three inches. Thus, the width of the sheet 16 between the rings must be related to this dimension and the ability to be folded over as here described. A width of about four (4) inches has proved satisfactory.

Referring to Figures 8—14 of the drawings wherein like numerals apply to like parts throughout, it will be seen that we have provided an improved wound edge protector 10 which can be manufactured in a few different sizes each of which is adjustable for use in incisions of varied size.

The protector 110 is comprised of a pair of flexible rings 112, 114 joined by a thin sheet 116 of flexible material. The rings can be formed by lengths of stock preformed to arcuate shape to give a preselected shape, when ready for use, as viewed in Figure 8, yet be resilient and flexible so as to be easily flexed for insertion through a wound opening as will presently be described. There are a number

of suitable plastics from which the rings can be made among which we have found nylon by way of example, as being highly suited to the purpose.

5 Each of the rods constituted by lengths of stock for the rings 112, 114 is of a preselected length designed to accommodate a certain range of incision sizes. The ring 112 is formed from a rod having its end formed with a reduced diameter section 144 which may be pre-
10 formed with the stock for the ring or provided by inserting stock of smaller diameter into hollow stock which is used for the ring proper. The opposing end of the rod for the ring 112
15 is hollow to telescopically receive the section 144 therein for adjustment purposes, as shown in detail in Figure 14. Of course the ring 114 is similarly formed for the same purpose.

The sheet 116 can be formed by cutting a flat sheet of selected stock to predetermined width. The longitudinal side edges respectively, are folded about the rings and sealed as
20 at 120, 121 in Figure 10, at least along a portion of its length, to thus provide a unitary structure ready for adjusted assembly.

The sheet 116 has a length generally comparable to the circumference of the rings but the end edge portions 123, 125 at one end are not sealingly wrapped around the rings
30 112, 114 but are free, as shown in Figure 11. Thus, the ends 144 can be telescoped into the cooperative opposing ends at the joints of the rings to give the desired size. The sheet transverse free end portion 127 can be overlapped
35 about the opposing end portion and its side portions 123, 125 wrapped around the telescoping ring portions. If the size of protector is excessively large, of course the inside end portion 129, as viewed in Figure 11 can be transversely cut to eliminate the excess and thus
40 give a higher degree of adjustability.

In a modified form of protector, the rings 112¹, 114¹ are non-telescopic. Each of the rods constituting the rings has one end provided
45 with a pair of clips 131, 133 which are bonded or otherwise unitarily formed therewith. The clips 131, 133 have open sides 135, 137 to receive the opposing ends of the rods constituting the rings, as by snapping the same into
50 the clips. The sheet 116¹ is joined to the rings in the same fashion as above described except the sheet stock does not envelope the clips 131, 133. Adjustment can be effected in an obvious fashion in view of the above description.

55 For the purpose of packaging, the protector can be compressed with one ring 112 against the other ring 114.

In use, the wound edge protector 110 is especially useful in abdominal incisions. Figure
60 13 shows a portion of a patient's abdomen at A with an incision having been made. The layers through which the incision is made include the skin 122, subcutaneous tissue 124, anterior fascia 126, muscle 128 and periton-
65 eum 130. At the incision these layers and the

adjacent interior and exterior surfaces 132, 134 respectively, constitute the wound edge.

The adjustable wound edge protector, after the incision is made, is adjusted to the size of the incision and is squeezed together so that
70 one of the rings 114 has its longitudinal side portion 136, 138 pressed together. The ring 114 can thus be inserted through the wound opening and allowed to expand to its normal form within the wound. The ring 114 will thus
75 be positioned on the inside of the peritoneum 130 over the surface portion 132 as seen best in Figure 13. The outer ring 112 will naturally similarly overlap the skin edge surface at 134 and the sheet 116 will contact the entire wound
80 surface and protectively cover the same and seal it from contamination and infection. Function in other respects is much as with the non-adjustable version.

In view of the foregoing it is believed that we have provided a wound edge protector which fulfils the objects hereinbefore enumerated.

The present invention also comprehends the wound edge protector maintained in a sterile
90 condition in a hermetically sealed package.

WHAT WE CLAIM IS:—

1. A wound edge protector comprising two resilient rings and a flexible sheet material formed into a substantially tubular shape, each
95 ring being connected to an end of the tube, and the material of the protector being sterilisable and at least the outer surface of the protector being non-irritating to wounds.

2. A wound edge protector according to claim 1, wherein each ring is formed from a flexible rod, one end of which is telescopically
100 received within the other end thereof.

3. A wound edge protector according to claim 1, wherein each ring is formed from a flexible rod, one end of which is releasably gripped by at least one clip provided at the
105 other end thereof.

4. A wound edge protector according to any one of claims 1 to 3 in which each of said rings is substantially oval in shape when re-
110 laxed.

5. A wound edge protector according to any one of claims 1 to 4 wherein said rings are made of a polyamide or a polytetrafluorethylene.
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6. A wound edge protector according to any one of claims 1 to 5 wherein said flexible sheet material is a polyvinyl plastic.

7. A wound edge protector according to any one of claims 1 to 6 wherein each of the opposed end edges of said sheet is folded back upon the sheet and about a respective one of
120 said rings and bonded to the sheet.

8. A wound edge protector according to any one of the preceding claims maintained in a sterile condition in a hermetically sealed package.

9. Wound edge protectors substantially as

hereinbefore described with reference to the accompanying drawings.

10. For use in forming a wound edge protector according to any one of the preceding claims, a pair of flexible rods, the ends or end portions of each rod being releasably connectable together to form one of said resilient rings and each rod being joined at least partly along the length thereof to an opposed end of a sheet of flexible material, the width of

which sheet is such that when the rods are formed into rings, the sheet is formed into a substantially tubular shape.

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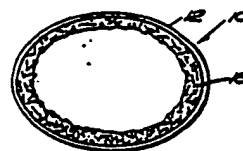


FIG. 1

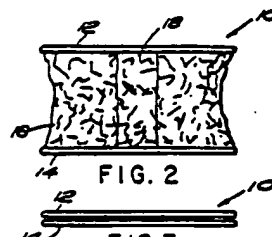


FIG. 2



FIG. 3

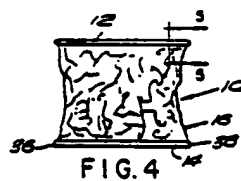


FIG. 4

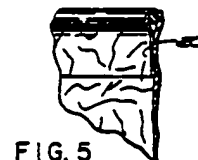


FIG. 5

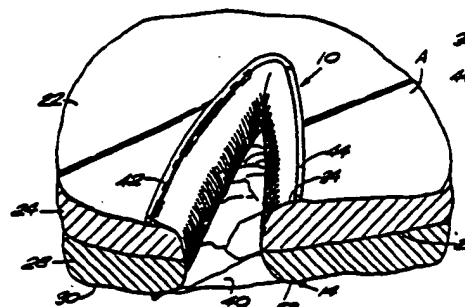


FIG. 6

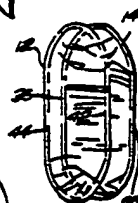
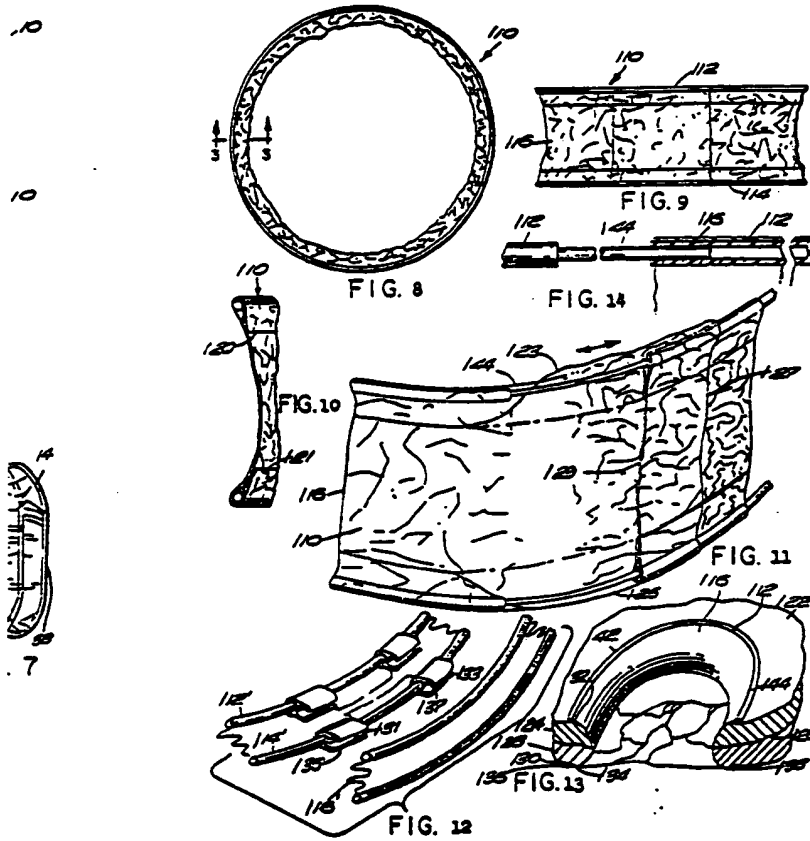


FIG. 7

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the Original on a reduced scale
Sheets 1 & 2



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